K001727

AUG 9 2000

# 510(K) SUMMARY
## (as required by 807.92(c))

**Submitter of 510(k):**

Blease Medical Equipment, Ltd.
Deansway, Chesham
Bucks, England, HP5 2NX

Phone: 44 1494774981
Fax: 44 1494791427

**Contact Person:** Richard Cooke

**Date of Summary:** April 10, 2000

**Trade Name:** Blease Frontline Genius Anesthesia Machine
Blease Medical Equipment, Ltd.
Deansway, Chesham
Bucks, England, HP5 2NX

**Classification Name:** Anesthesia Machine

**Predicate Device:** Blease Frontline Genius Range K982137

**Device Description/ Comparison:**

The Frontline Genius is identical to the cleared Frontline Genius Anesthesia Machine. A Validation for MRI use has been completed and this claim is added to the promotional material.

**Intended Use:**

The Blease Frontline Genius Range, Anesthesia Machines are intended for use in the hospital environment and locations not requiring portability. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient-breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 9 2000

Mr. Arthur J. Ward
Blease Medical Equipment Ltd.
c/o AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Re: K001727
Blease Anesthesia Unit
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: July 14, 2000
Received: July 17, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**510(k) Number (if known):** K001727

**Device Name:** Blease Frontline Genius Range, Anesthesia Machines

**Indications For Use:**

The Blease Frontline Genius Range, Anesthesia Machines are intended for use in the hospital environment and locations not requiring portability. It may be used for the delivery of oxygen, air and nitrous oxide in a controlled manner to various patient-breathing circuits with or without the use of a mechanical ventilator, and may be used for the delivery of anesthetic vapor by use of a dismountable vaporizer.

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001727

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)